

A. GENERAL

1. Please prepare a summary of the status of the State's or Region's actions taken in response to each of the open recommendations from previous IMPEP reviews.

2018 Recommendation 1: The team recommends that the NYC inspectors obtain additional training regarding the application of DOT regulations to material licensee inspections and take steps to properly perform associated inspections (Section 3.3).

NYC inspectors have received additional training regarding the application of DOT regulations since the 2018 review. One inspector and one license reviewer have taken the NRC training class (H-308S - transportation), and two inspectors have taken alternate training (a course on radioactive materials transport regulations offered by a local vendor). NYC has reinforced with inspection staff the need to verify compliance with transportation regulations, and indicate compliance status on the inspection form.

2018 Recommendation 2: The team recommends that the Program make appropriate regulatory changes to resolve NRC-generated comments as noted in regulation review letters, and adopt NRC regulations in accordance with the current NRC policy on adequacy and compatibility (Section 4.1 of the 2014 IMPEP report).

NYC Regulations in Article 175 have been completely revised to be compatible with NRC regulations, using a "cite by reference" approach to incorporate the text of NRC regulations in 10CFR into NYC code. The revised regulations took effect on May 24, 2019.

The regulatory changes took longer than initially anticipated because the repeal and reenactment of Article 175 was an extensive revision that integrated radioactive materials with radiation producing equipment, which hadn't been significantly updated since 1994. The first public hearing occurred in July 2018 and we received significant public comment. The finalization and adoption of the code was delayed to address stakeholder input. NYC conducted stakeholder meetings at both the adoption and implementation stages and developed an online FAQ document to further assist with implementation of the new code.

B. COMMON PERFORMANCE INDICATORS

I. Technical Staffing and Training

2. Please provide the following organization charts, including names and positions:

- (a) A chart showing positions from the Governor down to the Radiation Control Program Director;
- (b) A chart showing positions of the radiation control program, including management; and
- (c) Equivalent charts for sealed source and device evaluation, low-level radioactive waste and uranium recovery programs, if applicable.

(a)

- 1. Mayor (Eric Adams)
- 2. Commissioner of Health (Dr. Ashwin Vasan)
- 3. Deputy Commissioner for Environmental Health (Corinne Schiff)
- 4. Assistant Commissioner for Environmental Sciences and Engineering (Lily Huang)
- 5. Radiation Control Program Director (Mark Horberg)

(b) Organization Chart (see attached)

(c) N/A

3. Please provide a staffing plan, or complete a listing using the suggested format below, of the professional (technical) full-time equivalents (FTE) applied to the radioactive materials program by individual. Include the name, position, and, for Agreement States, the fraction of time spent in the following areas: administration, materials licensing & compliance, emergency response, low-level radioactive waste, uranium recovery, other. If these regulatory responsibilities are divided between offices, the table should be consolidated to include all personnel contributing to the radioactive materials program. If consultants were used to carry out the program's radioactive materials responsibilities, include their efforts. The table heading should be:

| <u>Name</u> | <u>Position</u> | <u>Area of Effort</u> | <u>FTE%</u> |
|-------------------------------|---|--|-------------|
| Lily Huang | Asst. Commissioner | Administration | 5 |
| Mark Horberg | Director, Office of Radiological Health | Administration | 50 |
| Stanley Chin | Director, Administration | Administration | 10 |
| Erik Finkelstein ^a | Unit Chief, Radioactive Materials | Administration | 40 |
| | | Materials Licensing & Compliance | 50 |
| Hailu Tedla ^a | City Research Scientist III | Materials Licensing & Compliance | 25 |
| | | Emergency response | 15 |
| Jose Lorenzo ^b | Scientist III | Administration (Supervision) | 25 |
| | | Materials Licensing & Compliance | 65 |
| Olga Aminev ^b | Scientist II | Materials Licensing & Compliance | 50 |
| Mark Rayman ^b | Scientist II | Materials Licensing & Compliance | 50 |
| Kimloan Nguyen ^{b,c} | Scientist II | Materials Licensing & Compliance | 25 |
| Dixitkumar Patel | City Research Scientist II | Materials Licensing & Compliance (anticipated) | 25 |
| | | Emergency Response | 30 |
| TBD (open position) | City Research Scientist II | Materials Licensing & Compliance | 50 |
| | | Emergency Response | 30 |

a: Qualified License Reviewer

b: Qualified Inspector

c: License Reviewer in training

d: No individual FTE is 100% for the radioactive materials program since all staff have some involvement with radiation producing equipment regulation.

4. Please provide a listing of all new professional personnel hired into your radioactive materials program since the last review, indicate the date of hire; the degree(s) they received, if applicable; additional training; and years of experience in health physics or other disciplines, as appropriate.

Sarah Bajwa, hired on 9/1/2020. MS degree in Environmental Health. Experience included 7 years in the public health field including emergency preparedness and radiation emergency planning. Previous basic radiation awareness/safety training.

Dixitkumar Patel, hired on 4/7/2022. MS degree in Environmental Engineering. Experience includes hazardous materials testing, treatment, and site remediation.

5. Please list all professional staff who have not yet met the qualification requirements for a radioactive materials license reviewer or inspector. For each, list the courses or equivalent training/experience the staff need and a tentative

schedule for completion of these requirements.

Kimloan Nguyen (inspector, in training as license reviewer), fully qualified as inspector for basic inspections (basic medical offices). Ms. Nguyen requires additional supervised experience for some inspections, such as for 35.600 uses. Ms. Nguyen was also being trained as license reviewer, but training was put on hold after March 2020 due to the pandemic. There is no current plan to complete this training.

Sarah Bajwa (trainee license reviewer), completed the required NRC agreement state training, still needed more supervised on-the-job experience reviewing different types of license actions. Left the agency as of May 2022.

Dixitkumar Patel (trainee license reviewer), will be scheduled for NRC Agreement State training.

6. Identify any changes to your qualification and training procedure that occurred during the review period.

N/A.

7. Please identify the technical staff that left your radioactive materials program during the review period and indicate the date they left.

Regina Alam (Director Office of Radiological Health) left the agency in June 2019. The vacancy was filled by Mark Horberg.

Christanna Kendrot (license reviewer in training, equipment manager and emergency preparedness specialist) was promoted to Unit Chief, Radiation Producing Equipment. The vacancy was filled by Sarah Bajwa.

Sarah Bajwa (license reviewer in training, equipment manager and emergency preparedness specialist) left the Agency in May 2022.

8. List any vacant positions in your radioactive materials program, the length of time each position has been vacant, and a brief summary of efforts to fill the vacancy.

The City Research Scientist II position (license reviewer in training, equipment manager and emergency preparedness specialist) formerly held by Sarah Bajwa, has been vacant since May 23, 2022. We have received permission from DOHMH to fill the position.

9. For Agreement States, does your program have an oversight board or committee which provides direction to the program and is composed of licensees and/or

members of the public? If so, please describe the procedures used to avoid any potential conflict of interest.

N/A.

II. Status of Materials Inspection Program

10. Please identify individual licensees or categories of licensees the State is inspecting less frequently than called for in NRC's Inspection Manual Chapter (IMC) 2800 and explain the reason for the difference. The list only needs to include the following information: license category or licensee name and license number, your inspection interval, and rationale for the difference.

N/A.

11. Please provide the number of routine inspections of Priority 1, 2, and 3 licensees, as defined in IMC 2800 and the number of initial inspections that were completed during each year of the review period.

| | 2018 (3/24/18 - 12/31/18) | 2019 | 2020 | 2021 | 2022 (as of 6/10/22) |
|----------------------|------------------------------|------|------|------|-------------------------|
| Initial | 16 | 18 | 1 | 17 | 8 |
| Routine - Priority 1 | n/a | n/a | n/a | n/a | n/a |
| Routine - Priority 2 | 18 | 16 | 8 | 21 | 6 |
| Routine - Priority 3 | 18 | 36 | 12 | 19 | 10 |
| Routine - Priority 5 | 66 | 112 | 46 | 124 | 42 |

(Initial inspections are not included in the number of routine inspections)

12. Please submit a table, or a computer printout, that identifies inspections of Priority 1, 2, and 3 licensees and initial inspections that were conducted overdue.

Three cycle inspections were conducted overdue (all of priority 2 licenses, specifically PET production / cyclotron facilities). See table below.

| License # | Licensee | Date inspected | Days overdue (per IMC2800) |
|------------|--|----------------|-------------------------------|
| 52-2955-06 | NYU School of Medicine | 12/14/2020 | 211 |
| 52-2968-04 | Memorial Sloan-Kettering Cancer Center | 1/11/2021 | 199 |
| 52-2968-06 | Memorial Sloan-Kettering Cancer Center | 1/11/2021 | 37 |

5 initial inspections were performed overdue (more than one-year past license issue date), in late 2020 and early 2021. These initial inspections were priority 5 licenses per NRC definition. All other inspections were within the scheduling window per IMC 2800.

13. Please submit a table or computer printout that identifies any Priority 1, 2, and 3 licensees-and initial inspections that are currently overdue, per IMC 2800. At a

minimum, the list should include the same information for each overdue inspection provided for Question 12 plus your action plan for completing the inspection. Also include your plan for completing the overdue inspections.

N/A.

14. Please provide the number of reciprocity licensees that were candidates for inspection per year as described in IMC 1220 and indicate the number of reciprocity inspections of candidate licensees that were completed each year during the review period.

Since NYC only regulates medical and non-commercial use of radioactive materials, there are few candidates for reciprocity inspections. Generally, NYC only inspects companies performing source exchange on medical devices (e.g. HDR).

Reciprocity inspections performed:

| 2018 (3/24/18 - 12/31/18) | 2019 | 2020 | 2021 | 2022 (to date) |
|---------------------------|------|------|------|----------------|
| 5 | 4 | 0 | 4 | 0 |

III. Technical Quality of Inspections

15. What, if any, changes were made to your written inspection procedures during the reporting period?

Due to the COVID-19 emergency, NYC developed a procedure for remote inspections, which was used for inspections between July 2020 and June 2021. After June 2021 we returned to onsite inspection procedures.

16. Prepare a table showing the number and types of supervisory accompaniments made during the review period. Include:

| <u>Inspector</u> | <u>Supervisor</u> | <u>License Category</u> | <u>Date</u> |
|------------------|-------------------|--------------------------------|-------------|
| INSPECTOR | SUPERVISOR | LICENSE CAT. (NRC priority) | DATE |
| Mark Rayman | Jose Lorenzo | Priority 5 | 11/7/18 |
| Olga Aminev | Jose Lorenzo | Priority 5 | 11/15/18 |
| Kimloan Nguyen | Jose Lorenzo | Priority 5 | 11/27/18 |
| Jose Lorenzo | Erik Finkelstein | Priority 5 | 12/19/18 |
| Mark Rayman | Jose Lorenzo | Priority 5 | 11/19/19 |
| Kimloan Nguyen | Jose Lorenzo | Priority 5 | 11/20/19 |
| Olga Aminev | Jose Lorenzo | Priority 2 | 11/21/19 |
| Jose Lorenzo | Erik Finkelstein | Priority 3 | 12/6/19 |

| | | | |
|--------------|------------------|------------|----------|
| Jose Lorenzo | Erik Finkelstein | Priority 2 | 10/28/21 |
| Mark Rayman | Jose Lorenzo | Priority 3 | 12/22/21 |
| Olga Aminev | Jose Lorenzo | Priority 2 | 12/21/21 |

17. Describe or provide an update on your instrumentation, methods of calibration, and laboratory capabilities. Are all instruments properly calibrated at the present time? Were there sufficient calibrated instruments available throughout the review period?

Inspectors currently carry Ludlum model 2241 survey meters with NaI gamma probe and G-M pancake probe and/or Thermo RadEye G electronic ratemeters. All instruments are sent out to qualified outside vendors for annual calibration. As of 6/10/22 most instruments have been recently sent out for calibration service and are expected to be returned calibrated by the end of June. There were sufficient calibrated instruments throughout the review period.

IV. Technical Quality of Licensing Actions

18. How many specific radioactive material licenses does your program regulate at this time?

274 (as of 6/10/22)

19. Please identify any major, unusual, or complex licenses which were issued, received a major amendment, were terminated, decommissioned, submitted a bankruptcy notification or renewed in this period.

New license issued:

- New York Presbyterian gamma knife, license number 93-2960-05

Major and unusual licenses renewed in this period:

- Mount Sinai Hospital, broad medical use, license number 75-2909-04
- Montefiore Medical Center, broad medical use, license number 75-2885-01
- Memorial Sloan-Kettering Cancer Center, broad medical use, license number 75-2968-01
- Long Island Jewish Medical Center, broad medical use license number 75-2986-01
- Columbia University / New York Presbyterian Hospital, broad medical use, license number 75-2878-01
- New York Presbyterian - Weill Cornell Hospital, broad medical use, license number 75-2960-04

- New York University Medical Center, broad medical use, license number 75-2955-01
- New York University, broad non-human use, license numbers 74-2955-02 and 74-2955-04
- Columbia University Medical Center, broad non-human use, license number 74-2878-03
- Hunter College, non-human use, license number 52-3120-02
- Memorial Sloan-Kettering Cancer Center, non-human use (PET production cyclotron), license number 52-2968-06
- New York University, non-human use (PET production cyclotron), license number 52-2955-06
- Columbia Presbyterian gamma knife, license number 93-2878-05
- New York University gamma knife, license number 93-2955-05

Other:

- Mount Sinai West / Mount Sinai Saint Lukes, broad medical use, license number 75-2898-01 - terminated and converted to two new limited-scope medical licenses (number 91-2898-02 and 91-3726-01)

20. Discuss any variances in licensing policies and procedures or exemptions from the regulations granted during the review period.

During the COVID-19 emergency, license expirations were temporarily waived. (This was a New York City policy for all types of permits, not just radioactive materials licenses.) This took effect in April 2020 and lasted until June 2021.

During the early months of the COVID-19 emergency, some licensees were told that we would allow them to skip a required periodic QA test or safety check if they could document the reason for non-performance.

In April 2020 one licensee (Mount Sinai Hospital) was granted permission to exceed the possession limit on their license for Lutetium-177. They had stated that due to COVID-19-related staff shortages, they had to do multiple procedures on one day rather than on different days.

21. What, if any, changes were made in your written licensing procedures (new procedures, updates, policy memoranda, etc.) during the reporting period?

N/A.

22. Identify by licensee name and license number any renewal applications that have been pending for one year or more. Please indicate why these reviews have been delayed and describe your action plan to reduce the backlog.

N/A.

V. Technical Quality of Incident and Allegation Activities

23. For Agreement States, please provide a list of any reportable incidents not previously submitted to NRC (See Procedure SA-300, *Reporting Material Events*, for additional guidance, OMB clearance number 3150-0178). The list should be in the following format:

| <u>Licensee Name</u> | <u>License #</u> | <u>Date of Incident/Report</u> | <u>Type of Incident</u> |
|----------------------|------------------|--------------------------------|-------------------------|
|----------------------|------------------|--------------------------------|-------------------------|

All reportable incidents have been submitted to NRC.

24. Identify any changes to your procedures for responding to incidents and allegations that occurred during the period of this review.

N/A.

C. NON-COMMON PERFORMANCE INDICATORS

I. Compatibility Requirements

25. Please list all currently effective legislation that affects the radiation control program. Denote any legislation that was enacted or amended during the review period.

NYC Health Code Article 175, repealed and replaced effective May 24 2019.

26. Are your regulations subject to a "Sunset" or equivalent law? If so, explain and include the next expiration date for your regulations.

N/A.

27. Please review and verify that the information in the enclosed State Regulation Status (SRS) sheet is correct. For those regulations that have not been adopted by the State, explain why they were not adopted, and discuss actions being taken to adopt them. If legally binding requirements were used in lieu of regulations and they have not been reviewed by NRC for compatibility, please describe their use.

The current regulation (Article 175 newly adopted as of May 2019) uses a "cite by reference" format to incorporate the text of NRC regulations required for compatibility into NYC code.

28. If you have not adopted all amendments within three years from the date of NRC rule promulgation, briefly describe your State's procedures for amending regulations in order to maintain compatibility with the NRC, showing the normal length of time anticipated to complete each step.

N/A (see previous answer)

II. Sealed Source and Device (SS&D) Evaluation Program N/A

29. Prepare a table listing new and amended (including transfers to inactive status) SS&D registrations of sources and devices issued during the review period. The table heading should be:

| SS&D Registry of <u>Number</u> | Manufacturer, Distributor or <u>Custom User</u> | Product Type <u>or Use</u> | Date <u>Issued</u> | Type <u>Action</u> |
|---|---|-------------------------------|-----------------------|-----------------------|
|---|---|-------------------------------|-----------------------|-----------------------|

30. Please include information on the following questions in Section A, as they apply to the SS&D Program:

Technical Staffing and Training - Questions 2-9
Technical Quality of Licensing Actions - Questions 18-22
Technical Quality of Incident and Allegation Activities - Questions 23-24

III. Low-level Radioactive Waste Disposal Program N/A

31. Please include information on the following questions in Section A, as they apply to the Low-Level Radioactive Waste Disposal Program:

Technical Staffing and Training - Questions 2-9
Status of Materials Inspection Program - Questions 10-14
Technical Quality of Inspections - Questions 15-17
Technical Quality of Licensing Actions - Questions 18-22
Technical Quality of Incident and Allegation Activities - Questions 23-24

IV. Uranium Recovery Program N/A

32. Please include information on the following questions in Section A, as they apply to the Uranium Recovery Program:

Technical Staffing and Training - Questions 2-9
Status of Materials Inspection Program - Questions 10-14
Technical Quality of Inspections - Questions 15-17
Technical Quality of Licensing Actions - Questions 18-22
Technical Quality of Incident and Allegation Activities - Questions 23-24

MATERIALS REQUESTED TO BE AVAILABLE FOR THE ON-SITE PORTION OF AN IMPEP REVIEW

Please have the following information available for use by the IMPEP review team when they arrive at your office:

- List of open license cases, with date of original request, and dates of follow-up actions.
- List of licenses terminated during review period.
- Copy of current log or other document used to track licensing actions.
- List of all licensing actions completed during the review period (sorted by license reviewer, if possible).
- Copy of current log or other document used to track inspections.
- List of all inspections completed during the review period (sorted by inspector, if possible).
- List of inspection frequencies by license type.
- List of all allegations occurring during the review period. Show whether the allegation is open or closed and whether it was referred by NRC.
- List of all licenses that your agency has imposed additional security requirements upon.

ALSO, PLEASE HAVE THE FOLLOWING DOCUMENTS AVAILABLE:

- All State regulations
- Statutes affecting the regulatory authority of the State program
- Standard license conditions
- Technical procedures for licensing, model licenses, review guides
- SS&D review procedures, guides, and standards
- Instrument calibration records
- Inspection procedures and guides
- Inspection report forms
- Documented training plan, if applicable
- Records of results of supervisory accompaniments of inspectors
- Emergency plan and communications list
- Procedures for investigating allegations
- Procedures for investigating incidents
- Enforcement procedures, including procedures for escalated enforcement, severity levels, civil penalties (as applicable)
- Job descriptions